UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

LAURA L. BRILL, *Individually and on Behalf of All Others Similarly Situated*, Plaintiff, v. INVIVYD, INC., TILLMAN U. GERNGROSS, and LAURA WALKER, Defendants.	)	No. 1:23-cv-10254-JEK

MEMORANDUM AND ORDER ON DEFENDANTS' MOTION TO DISMISS

KOBICK, J.

This is a putative class action lawsuit alleging violations of sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and Securities and Exchange Commission Rule 10b-5. Defendant Invivyd, Inc. (at all relevant times called Adagio Therapeutics, Inc.) is a biopharmaceutical company that, in 2021, developed a monoclonal antibody therapy for the prevention and treatment of COVID-19. Adagio's lead product candidate, ADG20, had been successful in combatting the original strain of SARS-CoV-2 and its early variants, including Alpha, Beta, Delta, and Gamma. When the Omicron variant emerged in November 2021, Adagio and the individual defendants optimistically predicted that ADG20 would continue to be effective against the new variant. They made several public statements to that effect on November 29 and December 1, 2021, only to reveal on December 14, 2021 that *in vitro* testing results demonstrated a 300-fold reduction in ADG20's effectiveness against Omicron. Adagio's common stock price increased from $25.12 to

$46.83 per share following defendants' statements on November 29, 2021, and then fell to $5.57 per share by December 15, 2021 after the release of the *in vitro* results.

The lead plaintiffs and putative class members purchased stock of Adagio during the November 29 to December 14, 2021 class period. In their second amended complaint, the plaintiffs allege that the defendants' November 29 and December 1, 2021 statements were materially false or misleading, in violation of section 10(b), Rule 10b-5, and section 20(a). Pending before the court is the defendants' motion to dismiss the second amended complaint with prejudice and without leave to amend. The defendants contend, and the Court agrees, that the plaintiffs fail to allege that the defendants' statements were materially false or misleading under the heightened pleading standards required under Federal Rule of Civil Procedure 9(b) and the Private Securities Litigation Reform Act, 15 U.S.C. § 78u-4(b). The plaintiffs also fail to allege facts sufficient to show that the defendants acted with the requisite scienter. The defendants' motion will therefore be granted.

BACKGROUND

I. Factual Background.

The pertinent facts, as alleged in the second amended complaint, are as follows. Lead plaintiffs Robyn Fizz and Gerald Hass and putative class members purchased common stock of Adagio Therapeutics, Inc. between November 29 and December 14, 2021 (the "Class Period"). ECF 32, ¶¶ 1, 6-7. Defendant Invivyd, Inc.—then called Adagio Therapeutics, Inc.—is a clinical-stage biopharmaceutical company that, during the Class Period, was focused on developing a monoclonal antibody therapy to prevent and treat COVID-19. *Id.* ¶¶ 8, 30.[1] Defendant Tillman

[1] Adagio announced that it was changing its corporate name to Invivyd, Inc. in September 2022. ECF 32, ¶ 8. Since Invivyd's corporate name during the class period was Adagio, the Court uses Adagio to refer to Invivyd. *Id.*

Gerngross is a co-founder of Adagio and, during the Class Period, served as its Chief Executive Officer and a member of the Board of Directors. *Id.* ¶ 9.[2] Defendant Laura Walker is also a co-founder of Adagio and, during the Class Period, served as its Chief Scientific Officer. *Id.* ¶ 10.

A. Adagio and the Development of ADG20.

Adagio was founded in June 2020, in the throes of the COVID-19 pandemic, to develop drugs for treating and preventing COVID-19 and future coronavirus outbreaks. *Id.* ¶ 30. It conducted an initial public offering ("IPO") on August 6, 2021, and as part of the IPO, filed with the Securities and Exchange Commission ("SEC") a Form S-1 Registration Statement on July 16, 2021 and its SEC Rule 424(b)(4) final prospectus (the "Prospectus"), *see* 17 C.F.R. § 230.424, on August 6, 2021, ECF 32, ¶ 31.

During the Class Period, Adagio's lead product candidate was ADG20. ECF 32, ¶ 32. According to the Prospectus, "ADG20 [was] designed to be a potent, long-acting and broadly neutralizing antibody for both the treatment and prevention of COVID-19 as either a single or combination agent." *Id.*; *see also* Adagio Therapeutics, Inc., Prospectus (Form 424B4) (Aug. 6, 2021). At the time, most available antibody treatments for COVID-19, including ADG20, targeted the "spike protein" of the SARS-CoV-2 virus. ECF 32, ¶ 20. The spike protein is the structural portion of the SARS-CoV-2 virus that enables it to enter a human host cell and begin replicating. *Id.* ¶¶ 20, 22. The spike protein of the SARS-CoV-2 virus works by binding to an enzyme known as the Angiotensin Converting Enzyme 2 ("ACE2") that is found in many types of human cells. *Id.* ¶ 22. The specific region within the spike protein that binds with ACE2 in the human body is known as the Receptor Binding Domain ("RBD"). *Id.* ¶ 23. The spike protein's RBD is thus key to SARS-CoV-2's ability to infect a person. *Id.*

[2] Dr. Gerngross resigned from Adagio on February 18, 2022. ECF 32, ¶ 9.

"Neutralizing antibodies," such as ADG20, generally prevent viral infection by targeting and binding to the regions of the spike protein that the virus uses to enter the host cell, thereby blocking the spike protein from entering the cell. *Id.* ¶ 24. If a spike protein mutates significantly—and especially if that mutation occurs within the RBD—that can prevent antibodies from binding to the virus and thereby render the antibodies ineffective in preventing infection of the host cell. *Id.* ¶¶ 26-27. Mutations that have this effect are known as "escape" mutations. *Id.* ¶ 26. As new variants of the virus emerge, those variants may or may not contain the escape mutations of earlier variants. *See id.* ¶ 28. Nevertheless, neither the presence nor the absence of a particular mutation is a certain predictor of whether a new variant will have viral escape characteristics. *See id.* Therefore, as alleged in the second amended complaint, whether a new variant of a virus is resistant to particular antibodies is impossible to know absent laboratory testing and confirmation. *Id.* ¶ 29.

Adagio's August 6, 2021 Prospectus stated that in "*in vitro* studies, ADG20 ha[d] demonstrated neutralizing activity against SARS-CoV-2 and the emerging variants that ha[d] been associated with lower efficacy rates of certain vaccines and [were] resistant or partially resistant to a subset of [then] available or clinical stage [monoclonal antibodies]." *Id.* ¶ 32; Adagio Therapeutics, Inc., Prospectus (Form 424B4) (Aug. 6, 2021). The Prospectus further provided that "[u]nlike other antibody-based therapies specifically targeting SARS-CoV-2, ADG20 ha[d] demonstrated an ability in non-clinical studies to neutralize SARS-CoV-2, including variants of concern," and that "ADG20 maintained neutralization activity across all variants tested to date," including the Alpha, Beta, Gamma, and Delta variants. ECF 32, ¶¶ 33-34 (emphasis omitted); Adagio Therapeutics, Inc., Prospectus (Form 424B4) (Aug. 6, 2021).[3]

[3] The World Health Organization ("WHO") and the United States Centers for Disease Control and Prevention ("CDC") classify variants into different categories, the most common of which are "variants of interest" and "variants of concern." ECF 32, ¶ 18. The WHO defines a "variant of

At investor conferences following Adagio's IPO, Dr. Gerngross, Dr. Walker, and other Adagio executives presented data on and discussed ADG20's efficacy against COVID-19 and the then-existing variants. ECF 32, ¶ 37. At a conference on September 15, 2021, Dr. Walker stated that ADG20 was "maintaining its potency" against "many other variants, including Lambda variant, the new variant, Beta, Gamma, et cetera, the major ones that have been described," and represented that Adagio did not "have any concerns to date in terms of lack of activity against variants." *Id.* At a conference on October 6, 2021, Dr. Walker likewise represented that Adagio was "continually testing [ADG20] against new variants of concern and variants of interest," and that "so far," ADG20 had "maintained activity within five-fold of the original . . . virus [and] against all of the current variants of concern." *Id.* ¶ 38. At a conference on November 16, 2021, Dr. Walker similarly stated, "so far we've seen that ADG20 retains its activity across a very large panel of these different variants at least within five-fold of the original . . . virus." *Id.* ¶ 39. At the time of these statements, the prominent variants were the Alpha, Beta, Delta, and Gamma variants, each of which had relatively few mutations in the spike protein and within the RBD. *Id.* ¶ 40.

B. The Emergence of the Omicron Variant.

On November 4, 2021, scientists in South Africa began to see samples of SARS-Co-V-2 that looked different from previous variants, and on November 24, 2021, after several weeks of

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interest" as a variant "with genetic changes that are predicted or known to affect virus characteristics such as transmissibility, disease severity, immune escape, diagnostic or therapeutic escape," and "that has been identified as causing community transmission or multiple COVID-19 clusters, in multiple countries with increasing relative prevalence alongside increasing number of cases over time, or other apparent epidemiological impacts to suggest an emerging risk to public health." *Id.* The WHO defines a "variant of concern" as a variant that meets the definition of a variant of interest and is associated with at least one of the following changes at a degree of global health significance: "increase in transmissibility or detrimental change in COVID-19 epidemiology," "increase in virulence or change in clinical disease presentation," "decrease in effectiveness of public health and social measures or available diagnostics, vaccines, [and] therapeutics." *Id.*

monitoring and testing, they reported the new SARS-CoV-2 strain to the World Health Organization. *Id.* ¶¶ 42-43. On November 26, 2021, WHO's Technical Advisory Group on SARS-CoV-2 Virus Evolution designated the variant a variant of concern and named it Omicron. *Id.* ¶ 45. As of November 25, 2021, there were over eighty possible cases of Omicron, with the majority of cases concentrated in South Africa. *Id.* ¶ 44. Within a month, however, the CDC would estimate that Omicron represented 58.6% of the COVID-19 cases reported in the United States. *Id.*

Omicron differed from the Alpha, Beta, Delta, and Gamma variants in that it had three to four times as many mutations in the spike protein and three to ten times as many mutations in the RBD as those prior variants. *Id.* ¶ 46. Indeed, thirty-six of the Omicron variant's mutations occurred in the spike protein and ten of those mutations were located in the RBD. *Id.* Alpha, Beta, Delta, and Gamma each had no more than twelve mutations in the spike protein, no more than three of which were located in the RBD. *Id.* Moreover, four of Omicron's mutations occurred within the epitopes—the specific locations within the RBD to which antibodies bind—indicating that antibodies, like ADG20, could be less effective or completely ineffective against Omicron. *Id.* ¶ 49.

Accordingly, public health leaders began to warn that Omicron's mutations could make it resistant to then-existing vaccines and antibodies. *Id.* ¶ 47. On November 28, 2021, during an interview with *Fox News Sunday*, Dr. Francis Collins, Director of the National Institutes of Health, counseled the public to receive vaccines and booster shots while noting that Omicron had set a "new record in terms of the number of mutations," with "more than thirty of those in the spike protein," and therefore "might not respond as well to protection from the vaccines." *Id.* (emphasis omitted). On November 29, 2021, Dr. Anthony Fauci, Chief Medical Advisor to the President, was asked, during an interview with NBC's *Meet the Press*, what made Omicron more concerning than

previous variants of interest. *Id.* ¶ 48. Dr. Fauci responded by noting that Omicron had "32 or more" mutations in the spike protein, with "10 or more" mutations in the RBD, meaning the "profile of [Omicron's] mutations strongly suggest[ed] . . . that it might evade immune protection that you would get, for example, from a monoclonal antibody." *Id.* (emphasis omitted).

C. Adagio's Statements Regarding the Efficacy of ADG20 Against Omicron.

1. *November 29, 2021 Statements.*

On November 29, 2021, the first day of the Class Period, Adagio issued a press release regarding ADG20 neutralization and the Omicron variant ("November 29 Press Release"). *Id.* ¶ 50; *see* ECF 38-2. In that release, Adagio announced that "[d]ue to the highly conserved and immunorecessive nature of the epitope recognized by ADG20, [Adagio] expect[ed] that ADG20 [would] retain activity against Omicron, as [it] ha[d] observed in *in vitro* models with all other variants of concern identified previously," and that "none of the mutations present in . . . the Omicron variant ha[d] been associated with escape from ADG20 neutralization." ECF 32, ¶ 50 (emphasis omitted); ECF 38-2, at 1. The release further provided that "[b]ased on published epitope mapping and structural studies, Adagio anticipate[d] that ADG 20 [would] retain neutralizing activity against the Omicron variant whereas other [monoclonal antibody] products may lose substantial activity against this variant." ECF 32, ¶ 51 (emphasis omitted); ECF 38-2, at 1.

Also on November 29, 2021, Dr. Gerngross was interviewed on *The Exchange*, a CNBC program, and made various statements regarding ADG20, Omicron, and the November 29 Press Release ("November 29 Gerngross CNBC Statements"). ECF 32, ¶ 52. When asked how ADG20 was developed and why it had "the ability not to be affected" by mutated variants like Omicron, Dr. Gerngross responded, in part: "We very early on appreciated the potential danger from variants

emerging, and you see this with many infectious diseases in particular, in fact, coronaviruses. So we from the beginning sort of thought about that possibility and decided to design a molecule that is broadly neutralizing across the entire class of these SARS-like viruses." *Id*. (emphases omitted). Dr. Gerngross continued: "What we sought to find is a molecule that neutralizes SARS-1 as well as SARS-CoV-2 and targets a very unique site that the virus has not been able to change a lot without losing fitness. And so we target this highly conserved epitope and [ADG20] as shown to be resilient, to date, against any of the variants that have emerged." *Id.* (emphasis omitted). Dr. Gerngross also said, "[w]hat we know is that our antibody, based on a sequence analysis, is likely to bind [Omicron] and not lose any of its neutralization potency." *Id.* ¶ 54. (emphasis omitted). Dr. Gerngross highlighted "the remarkable half-life of the [ADG20] antibody" and its "ability of being injected once" and that "after six months[,] the neutralization titers of [ADG20] are significantly higher than we see with any of the vaccines." *Id.* ¶ 55 (emphasis omitted).

In addition, the *Boston Business Journal* published an article on November 29, 2021 regarding ADG20 that contained quotes from Dr. Gerngross ("November 29 Gerngross BBJ Statements"). *See id.* ¶ 56; ECF 38-5. The article reported that Adagio was "riding high after the company said its experimental antibody [was] likely to be just as effective against the omicron variant of the coronavirus as it [was] against previous variants," and had "sai[d] that ADG20 ha[d] so far been effective against the ancestral strain of SARS-CoV-2 (the scientific name for the novel coronavirus) as well as the alpha, beta, delta and gamma variants." ECF 38-5, at 2-3. It quoted Dr. Gerngross as stating: "We, from the beginning, predicted exactly what is happening now. We said that the Greek alphabet has 24 letters, and we have a long way to go. . . . The only way to really hedge against the viral escape that we're seeing is to come up with antibodies that target residues on the [RBD]," and that Adagio "did the work to do that" and "ended up engineering antibodies

that are extremely potent and have th[at] broad recognition." *Id.* at 3. Dr. Gerngross was also quoted as saying, "[ADG20] neutralized SARS 1. It will neutralize SARS-CoV-2 and all its known variants. . . . That's the strategy we had articulated at the beginning." *Id.*; ECF 32, ¶ 56 (emphasis omitted).

2. *December 1, 2021 Statements.*

On December 1, 2021, Dr. Gerngross, Dr. Walker, and other Adagio executives spoke at the Evercore ISI Fourth Annual HealthCONx Conference ("December 1 Gerngross Evercore Statements"). ECF 32, ¶ 57; ECF 38-6. In his opening remarks, Dr. Gerngross stated that a "major aspect of the [ADG20] program was to create a molecule that deals with all the variants by designing something that is broadly neutralizing, hitting a unique capital that has been highly conserved and therefore is less likely to result in [viral escape] and that's what [Adagio had] seen up to [that] point." ECF 32, ¶ 57 (emphasis omitted); ECF 38-6, at 1. He continued, "[t]he data on [Omicron] as far as localization [was] yet to come, but everything that [they had] seen so far up to [that] point where [they] look for all in terms of having been able to neutralize all the other variants." ECF 32, ¶ 58 (emphasis omitted); ECF 38-6, at 1-2.

D. December 2021 *In Vitro* Test Findings and Related December 14, 2021 Statement.

Researchers at the University of Oxford were the first to evaluate whether the Omicron variant escaped from ADG20. ECF 32, ¶ 59(b). As reflected in its public filings, Adagio did not conduct its own testing and relied on third parties to "conduct, supervise, analyze, and monitor a significant portion of [Adagio's] research and preclinical testing and clinical trials for [Adagio]'s product candidates," and Adagio did not "own or operate any facilities for product . . . testing." *Id.* ¶ 59(a). Accordingly, Adagio provided ADG20 to several groups of third-party researchers, including those at Oxford. *Id.* ¶ 59(b).

Ultimately, the Oxford research showed that ADG20's neutralization activity against Omicron was reduced by 276-fold, which was a significant departure from its effectiveness against the previous variants. *Id.* Oxford informed Adagio of its findings on December 9, 2021. *Id.* ¶ 59(c). Five days later, on December 14, 2021, Adagio issued a press release reporting the *in vitro* results of ADG20 against the Omicron variant (the "December 14 Press Release"). *Id.* ¶ 62; *see* ECF 38-7. In that release, Adagio announced that "[t]he *in vitro* data generated through both authentic and pseudovirus testing of the Omicron variant show a greater than 300-fold reduction in neutralizing activity of ADG20 against Omicron." ECF 32, ¶ 62; ECF 38-7, at 1. The release also contained a quote from Dr. Gerngross explaining, "[w]hile the individual mutations present in . . . Omicron . . . were not associated with escape from ADG20 in the context of an original strain of the virus, new data show that the combination of mutations present in the Omicron spike protein led to a reduction in ADG20 neutralization that was not suggested by prior data." ECF 32, ¶ 62; ECF 38-7, at 1.

E. Impact on Adagio Stock Price.

Adagio's statements about ADG20's efficacy against Omicron coincided with changes to Adagio's common stock price. On November 29, 2021—the day of the November 29 Press Release, the November 29 Gerngross CNBC Statements, and the November 29 Gerngross BBJ Statements—Adagio's common stock price increased to $46.83 per share, up from $25.12 per share on November 26, 2021. *Id.* ¶ 61. Adagio's common stock then continued to trade at high levels, trading as high as $78.82 per share on November 30, 2021. *Id.* ¶ 76. Then, on December 14, 2021—the day of the December 14 Press Release—Adagio's common stock dropped to $7.26 per share at market close, down from $34.26 per share at market close the day before. *Id.* ¶ 63. As the market continued to digest the news, the price of Adagio common stock continued to decline, falling to an intraday low of $5.57 per share by December 15, 2021. *Id.*

II. Procedural History.

The original complaint in this case was filed on January 31, 2023. ECF 32. On June 28, 2023, the Court appointed Robyn Fizz and Gerald Hass as lead plaintiffs. ECF 24. With leave of the Court, the plaintiffs filed an amended complaint on August 23, 2023, ECF 28, and the operative second amended complaint on November 22, 2023 (the "SAC"), ECF 32. The SAC alleges that Invivyd (Adagio) and the individual defendants, Dr. Gerngross and Dr. Walker, violated section 10(b) of the Securities Exchange Act of 1934 and Rule 10b-5 (Count I); and that Dr. Gerngross and Dr. Walker violated section 20(a) of the Securities Exchange Act of 1934 (Count II). ECF 32, ¶¶ 85-97. On January 12, 2024, the defendants moved to dismiss the complaint with prejudice and without leave to amend. ECF 36.

DISCUSSION

The plaintiffs allege violations of the federal securities laws—namely, sections 10(b) and 20(a) of the Securities Exchange Act of 1934, 15 U.S.C. §§ 78j(b), 78t(a), and Rule 10b-5 promulgated thereunder, 17 C.F.R. § 240.10b-5. Section 10(b) makes it unlawful to "use or employ, in connection with the purchase or sale of any security . . . any manipulative or deceptive device or contrivance in contravention of such rules and regulations as the [SEC] may prescribe as necessary or appropriate in the public interest or for the protection of investors." 15 U.S.C. § 78j(b). Rule 10b-5, in turn, makes it unlawful "(a) [t]o employ any device, scheme, or artifice to defraud, (b) [t]o make any untrue statement of material fact or to omit to state a material fact necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading, or (c) [t]o engage in any act practice, or course of business which operates or would operate as a fraud or deceit upon any person, in connection with the purchase or sale of any security." 17 C.F.R. § 240.10b-5. "Rule 10b-5 'is coextensive with the coverage of

[section] 10(b).'" *Ponsa-Rabell v. Santander Sec. LLC*, 35 F.4th 26, 32 (1st Cir. 2022) (quoting *S.E.C. v. Zandford*, 535 U.S. 813, 816 n.1 (2002)).

"For a complaint to state a claim for securities fraud under section 10(b) and Rule 10b-5, it must plead six elements: (1) a material misrepresentation or omission; (2) scienter, or a wrongful state of mind; (3) a connection with the purchase or sale of security; (4) reliance; (5) economic loss; and (6) loss causation." *ACA Fin. Guar. Corp. v. Advest, Inc.*, 512 F.3d 46, 58 (1st Cir. 2008). A claim under section 20(a), which "imposes joint and several liability on persons in control of entities that violate the securities laws," is "derivative of an underlying violation of the securities laws." *Fire & Police Pension Ass'n of Colorado v. Abiomed, Inc.*, 778 F.3d 228, 246 (1st Cir. 2015). Where there is "no underlying 10b-5 violation," the "section 20(a) claim must fail." *ACA Fin. Guar. Corp.*, 512 F.3d at 68.

I. Pleading Standard Under the Private Securities Litigation Reform Act and Federal Rule of Civil Procedure 9(b).

To survive a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6), a complaint alleging claims under sections 10(b) and 20(a) and Rule 10b-5 must adhere not only to the pleading standards set forth in *Bell Atl. Corp. v. Twombly*, 550 U.S. 544 (2007), and *Ashcroft v. Iqbal*, 556 U.S. 662 (2009), but also to the heightened pleading requirements of Federal Rule Civil Procedure 9(b) and the Private Securities Litigation Reform Act of 1995 ("PSLRA"), 15 U.S.C. § 78u-5. *Shash v. Biogen, Inc.*, 84 F.4th 1, 10 (1st Cir. 2023). "[A]s with any 12(b)(6) inquiry," the court must "'accept well-pleaded factual allegations in the complaint as true and view all reasonable inferences in the plaintiffs' favor.'" *Hill v. Gonzani*, 638 F.3d 40, 55 (1st Cir. 2011) (quoting *ACA Fin. Guar. Corp.*, 512 F.3d at 58). The court may, however, supplement its review of the factual allegations in the complaint with materials the defendants filed in support of their motion, to the extent that they "include 'documents the authenticity of which are not disputed by the parties,'

'official public records,' and 'documents sufficiently referred to in the complaint.'" *Constr. Indus. & Laborers Joint Pension Tr. v. Carbonite, Inc.*, 22 F.4th 1, 4 (1st Cir. 2021) (quoting *Mehta v. Ocular Therapeutix, Inc.*, 955 F.3d 194, 198 (1st Cir. 2020)). The complaint "must contain sufficient factual matter, accepted as true, to 'state a claim for relief that is plausible on its face.'" *Iqbal*, 556 U.S. at 678 (quoting *Twombly*, 550 U.S. at 570). In addition, under Rule 9(b), "a party alleging fraud 'must state with particularity the circumstances constituting fraud' in the pleading, but '[m]alice, intent, knowledge, and other conditions of a person's mind may be alleged generally." *Hill*, 638 F.3d at 55 (quoting Fed. R. Civ. P. 9(b)).

The PSLRA—which Congress crafted "to curb frivolous, lawyer-driven litigation, while preserving investors' ability to recover on meritorious claims," *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 322 (2007)—goes further than Rule 9(b) with respect to the pleading requirements for the first two elements of claims under section 10(b) and Rule 10b-5, *Hill*, 638 F.3d at 55. To plead a material misrepresentation or omission (the first element) under the PSLRA, the complaint must "specify each statement alleged to have been misleading, the reason or reasons why the statement is misleading, and, if an allegation regarding the statement or omission is made on information and belief, the complaint shall state with particularity all facts on which that belief is formed." 15 U.S.C. § 78u-4(b)(1). To plead scienter (the second element), the complaint must "with respect to each act or omission . . . state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." *Id.* § 78u-4(b)(2)(A). "While under Rule 12(b)(6) all inferences must be drawn in plaintiffs' favor, inferences of scienter do not survive if they are merely reasonable, as is true when pleadings for other causes of action are tested by motion to dismiss under Rule 12(b)(6)." *ACA Fin. Guar. Corp.*, 512 F.3d at 59 (quotation marks omitted). The court "must engage in a comparative evaluation; it must consider, not only

inferences [of scienter] urged by the plaintiff . . . but also competing inferences rationally drawn from the facts alleged." *Tellabs*, 551 U.S. at 314. But "where there are equally strong inferences for and against scienter . . . the draw [is awarded] to the plaintiff." *ACA Fin. Guar. Corp.*, 512 F.3d at 59.

The PSLRA also creates a safe harbor for "forward-looking statements" under certain circumstances. *See* 15 U.S.C. § 78u-5. If a statement falls within the safe harbor, it cannot give rise to liability, even where the statement is fraudulent. *In re Stone & Webster Inc., Sec. Litig.*, 414 F.3d 187, 195 (1st Cir. 2005). Thus, the court may dismiss a complaint on grounds that the challenged statements are protected by the PSLRA safe harbor provisions, notwithstanding whether the complaint otherwise satisfies the pleading standards under the Federal Rules and the PSLRA. *See Leavitt v. Alnylam Pharm., Inc.*, 451 F. Supp. 3d 176, 186-87 (D. Mass. 2020) (noting that the court's analysis on scienter was only for completeness, as the applicability of the safe harbor provision meant plaintiffs had failed to state an actionable claim).

II. The Plaintiffs' Allegations.

The plaintiffs allege that the defendants' November 29 and December 1, 2021 statements regarding the projected efficacy of ADG20 against Omicron—namely, the November 29 Press Release, the November 29 Gerngross CNBC Statements, the November 29 Gerngross BBJ Statements, and the December 1 Gerngross Evercore Statements—were materially false and misleading or omitted material information, in violation of section 10(b) and Rule 10b-5. The defendants advance three principal arguments as to why the allegations set forth in the SAC are inadequate to state claims under section 10(b) and Rule 10b-5, each of which could independently serve as grounds for dismissal: (1) the relevant statements fall within the scope of the safe-harbor provisions of the PSLRA; (2) the relevant statements were not materially false or misleading; and

(3) facts alleged do not support a strong inference of scienter. Bypassing the defendants' safe harbor argument, the Court concludes that the facts alleged in the SAC do not plausibly show that the defendants made materially false or misleading statements or omissions, nor do they establish a strong inference of scienter.

A. Material Misrepresentations or Omissions.

To establish the first element of a section 10(b) and Rule 10b-5 claim—a material misrepresentation or omission—the plaintiffs "'must show that [the] defendants made a materially false or misleading statement or omitted to state a material fact necessary to make a statement not misleading.'" *Ponsa-Rabell*, 35 F.4th at 32-33 (quoting *Ganem v. InVivo Therapeutics Holdings Corp.*, 845 F.3d 447, 454 (1st Cir. 2017)). "'Information is material if a reasonable investor would have viewed it as having significantly altered the total mix of information made available.'" *Id.* at 33 (quoting *Mississippi Pub. Employees' Ret. Sys. v. Bos. Sci. Corp.*, 523 F.3d 75, 85 (1st Cir. 2008)). "[W]hether a statement is 'misleading' depends on the perspective of a reasonable investor." *Omnicare, Inc. v. Laborers Dist. Council Constr. Indus. Pension Fund*, 575 U.S. 175, 186 (2015). The court must consider the statement in light of its context. *See Ezra Charitable Tr. v. Tyco Int'l, Ltd.*, 466 F.3d 1, 7 (1st Cir. 2006); *In re Karyopharm Therapeutics Inc., Sec. Litigation*, 552 F. Supp. 3d 77, 87 (D. Mass. 2021), *aff'd sub nom. Thant v. Karyopharm Therapeutics Inc.*, 43 F.4th 214 (1st Cir. 2022). Because the defendants do not dispute that the November 29 and December 1, 2021 statements regarding ADG20's efficacy against Omicron were material, the Court focuses its analysis on whether the statements were false or misleading.

The defendants argue that their statements concerning ADG20's projected ability to neutralize against Omicron were not false or misleading because they were non-actionable expressions of scientific opinion. "[T]he most significant difference between statements of fact

and expressions of opinion is that 'a statement of fact ('the coffee is hot') expresses certainty about a thing, whereas a statement of opinion ('I think the coffee is hot') does not.'" *Carbonite, Inc.*, 22 F.4th at 7 (quoting *Omnicare, Inc.*, 575 U.S. at 183). "A reasonable person understands, and takes into account, the difference . . . between a statement of fact and one of opinion. She recognizes the import of words like 'I think' or 'I believe,' and grasps that they convey some lack of certainty as to the statement's content." *Omnicare, Inc.*, 575 U.S. at 187. In other words, "a statement of opinion is not misleading just because external facts show the opinion to be incorrect. Reasonable investors do not understand such statements as guarantees." *Id.* at 188. Nevertheless, "a reasonable investor may, depending on the circumstances, understand an opinion statement to convey facts about how the speaker has formed the opinion—or otherwise put, about the speaker's basis for holding that view. And if the real facts are otherwise, but not provided, the opinion will mislead its audience." *Id.* Thus, insofar as a statement of opinion "convey[s] three facts: that the speaker has such a belief; that the belief fairly aligns with the facts known to the speaker; and . . . that the speaker has made the type of inquiry that a reasonable investor would expect given the circumstances," a complaint must plausibly allege the falsity of at least one of these facts to survive a motion to dismiss. *Carbonite*, 22 F.4th at 7-8.

The relevant statements identified in the SEC are all statements of opinion. The November 29 Press Release says that Adagio "expect[ed]" and "anticipate[d]" that ADG20 would "retain neutralizing activity against the Omicron variant." ECF 32, ¶¶ 50-51 (emphases omitted); ECF 38-2, at 1. Similarly, in the November 29 Gerngross CNBC Statements, Dr. Gerngross said that ADG20 had been "shown to be resilient, *to date*, against any of the variants that ha[d] emerged," and that it was "*likely* to bind [Omicron] and not lose any of its neutralization potency." ECF 32, ¶¶ 54-55 (emphasis altered). And in the December 1 Gerngross Evercore Statements, Dr.

Gerngross told conference attendees that "[t]he data on [Omicron] as far as localization [was] *yet to come*, but everything that [they had] seen *so far up to [that] point*" was that ADG20 had "been able to neutralize all the other variants." *Id.* ¶ 58 (emphasis altered). The use of the emphasized terms—"expects," "anticipates," "to date," "likely," "yet to come," and "so far up to that point"—conveys "some lack of certainty" as to Adagio's statements, such that a reasonable investor would not interpret the defendants' statements to be guarantees regarding ADG20's efficacy against Omicron. *See Omnicare, Inc.*, 575 U.S. at 187.

Although a closer call, Dr. Gerngross's quotes in the *Boston Business Journal* (the November 29 Gerngross BBJ Statements), read in context, also convey a lack of certainty. Seemingly referencing the November 29 Press Release, the opening sentence of the article states, "Adagio Therapeutics Inc. is riding high after the company said its experimental antibody *is likely* to be just as effective against the omicron variant of the coronavirus as it is against previous variants." ECF 38-5, at 2 (emphasis added). While the article later included more forceful quotes from Dr. Gerngross, including that ADG20 "neutralized SARS 1," and "will neutralize SARS-CoV-2 and all its known variants," and "[t]hat's the strategy we had articulated at the beginning," a reasonable investor would not read Dr. Gerngross's statements—in the context of the full article and press release—as a guarantee that ADG20 would neutralize against the emergent Omicron variant. ECF 32, ¶ 56 (emphasis omitted); ECF 38-5, at 3.

A statement of scientific opinion, rather than fact, can nonetheless be false or misleading. *Carbonite*, 22 F.4th at 7. The Court must consider, therefore, what facts a reasonable investor would understand the defendants' statements regarding ADG20's efficacy against Omicron to convey, and whether the SAC sufficiently alleges that at least one of those facts is false. *Id.* at 7-8; *see also Shash*, 84 F.4th at 12 (following the approach set forth in *Carbonite*). A reasonable

investor would first understand the defendants' statements to convey the fact of their subjective belief—that is that Adagio, Dr. Gerngross, and Dr. Walker believed on November 29 and December 1, 2021 that ADG20 would effectively neutralize against Omicron based on the information available to them. *See Carbonite*, 22 F.4th at 7. But, as the defendants emphasize, the SAC contains no allegations indicating Adagio, Dr. Gerngross, or Dr. Walker did not sincerely believe their statements.

Second, a reasonable investor would understand the defendants' statements to convey that their belief "fairly align[ed] with the facts known to [them]" at the time. *Carbonite*, 22 F.4th at 7. As stated in the November 29 Press Release, the defendants' belief that ADG20 would retain neutralizing activity against Omicron was based on "published epitope mapping and structural studies," their understanding that "none of the mutations present in . . . the Omicron variant ha[d] been associated with escape from ADG20 neutralization," the fact that ADG20 had retained activity against "all other variants of concern identified previously," and their view that "the epitope recognized by ADG20" was of a "highly conserved and immunorecessive nature." ECF 32, ¶¶ 50-51 (emphases omitted); ECF 38-2. While the plaintiffs attack the validity of the defendants' ultimate conclusion, they do not allege that the factual bases for the defendants' expectations were false. Nor do they allege that the defendants knew, at the time they made the statements, that ADG20 would ultimately be ineffective against Omicron. *See* ECF 39, at 6-10. Thus, the plaintiffs have not adequately alleged that the defendants misrepresented their belief that ADG20's expected neutralization of Omicron "fairly align[ed] with the facts known to [them]." *Carbonite*, 22 F.4th at 7.

Third, a reasonable investor would understand the defendants to convey, based on the aforementioned statements, that they had "made the type of inquiry that a reasonable investor

would expect given the circumstances." *Id.* The plaintiffs contend that this suggestion amounted to a material misrepresentation or omission. The SAC alleges that prior to receiving the *in vitro* results from Oxford, the defendants should have known that ADG20 was likely going to be ineffective against Omicron because they could have and should have consulted published research that demonstrated ADG20's closely related predecessor antibody, ADG-2, was likely ineffective against Omicron. ECF 32, ¶ 59(g). Researchers at the Massachusetts Institute of Technology ("MIT"), the SAC alleges, did conduct such a study based on published ADG-2 research between late November and early December 2021, the results of which they submitted to *Cell Reports Medicine* on December 7, 2021. *Id.* ¶ 59(h). Since the MIT study was based on "known, available, and published research," the plaintiffs allege, it demonstrates the defendants could have and should have conducted a similar analysis before speaking on ADG20's effectiveness against Omicron, *id.*, as this was the "meaningful inquiry" reasonable investors would expect, ECF 39, at 8-9. The defendants' failure to inform investors that they had not conducted such research, the plaintiffs argue, rendered the defendants' opinion statements misleading.

The Court disagrees. A reasonable investor reading the defendants' opinion statements would not expect the defendants to have conducted all possible analyses before offering their predictions. The November 29 Press Release expressly warned that Adagio "may not actually achieve the plans, intentions or expectations disclosed in [its] forward-looking statements and [the reader] should not place undue reliance on [its] forward-looking statements," because they "involve risks that could cause [its] actual results to differ materially from the results described in or implied by the forward-looking statements, including . . . unexpected safety or efficacy data observed during preclinical studies or clinical trials." ECF 38-2, at 2 (emphasis omitted); *see Omnicare, Inc.*, 575 U.S. at 190 ("[A]n investor reads each statement within . . . a document,

whether of fact or of opinion, in light of all of its surrounding text, including hedges, disclaimers, and apparently conflicting information.").

Moreover, "[t]he securities laws do not impose a duty to conduct 'good science.'" *In re Sepracor, Inc. Sec. Litigation*, 308 F. Supp. 2d 20, 36 (D. Mass. 2004) (citation and quotation marks omitted); *see also Shash*, 84 F.4th at 17 ("[A] legitimate disagreement over scientific data does not give rise to a securities fraud claim." (quotation marks omitted)). While the plaintiffs may disagree with the defendants' scientific opinion that consulting published epitope mapping and structural studies was sufficient for purposes of forming their predictions about ADG20's effectiveness against Omicron, that disagreement does not show that the defendants failed to conduct the inquiry reasonable investors would expect. *See Kleinman v. Elan Corp., plc*, 706 F.3d 145, 154 (2d Cir. 2013) ("[Plaintiffs] may take issue with Defendants' researchers and scientists, but where a defendant's competing analysis or interpretation of data is itself reasonable, there is no false statement."); *Tongue v. Sanofi*, 816 F.3d 199, 214 (2d Cir. 2016) ("a dispute about the proper interpretation of data" does not render a statement misleading and cannot be a basis for liability); *City of Edinburgh Council v. Pfizer, Inc.*, 754 F.3d 159, 170 (3d Cir. 2014) (because "interim results showed 'circumstantial evidence of efficacy,' . . . disagreement . . . with the company's interpretation of the interim results is not sufficient to show defendants' interpretation lacked a reasonable basis"); *see also In re Karyopharm Therapeutics Inc. Sec. Litigation*, 552 F. Supp. 3d at 89 (concluding defendants' interpretation of data was a "non-actionable scientific opinion" even though the FDA disagreed with defendants at the time of their statements and defendants' view of the data may have been wrong). The SAC does not, therefore, plausibly allege that the defendants did not conduct "the type of inquiry that a reasonable investor would expect given the circumstances." *Carbonite*, 22 F.4th at 7.

The plaintiffs additionally argue that the defendants' statements were materially misleading because, as alleged in the SAC, Omicron's structure differed so substantially from the previous variants, particularly with respect to the number and location of its mutations, such that it was evident—at the time of the defendants' statements—that ADG20 was unlikely to neutralize Omicron. ECF 39, at 6-7. Since the defendants' statements were statements of opinion, however, the plaintiffs cannot establish they were misleading merely by emphasizing "external facts show[ing] [defendants'] opinion to be incorrect" at the time the statements were made. *Omnicare, Inc.*, 575 U.S. at 188. Nor can the plaintiffs establish that the defendants' opinion statements were misleading simply by identifying countervailing facts that the defendants omitted from their statements. *Id.* at 189-90. "Reasonable investors understand that opinions sometimes rest on a weighing of competing facts; indeed, the presence of such facts is one reason why an issuer may frame a statement as an opinion, thus conveying uncertainty." *Id.*

Nor were the defendants' statements misleading because they omitted the warnings of public health officials, like Dr. Fauci, that Omicron may be resistant to monoclonal antibodies like ADG20. "[I]t is not a material omission to fail to point out information of which the market is already aware." *Ponsa-Rabell*, 35 F.4th at 35 (quotation marks omitted) (concluding that defendants were "not under any duty to repeat information already known or readily accessible to investors" in the form of public statements that "plaintiffs' own complaint" identified); *Thant*, 43 F.4th at 225 (same). As the SAC itself alleges, several public health leaders warned—on at least two national television networks—that Omicron's mutations might render it resistant to available vaccine and antibody treatments. ECF 32, ¶¶ 47-48. Accordingly, the market was aware of that risk, and the defendants had no obligation to repeat such warnings.

As evidence that the defendants' statements were misleading, the plaintiffs also point to the Oxford *in vitro* testing results published two weeks later in the December 14 Press Release, which ultimately revealed "a greater than 300-fold reduction in neutralizing activity of ADG20 against Omicron." *Id.* ¶ 62; ECF 38-7, at 1. As reflected in the release, the defendants explained the results by noting, "[w]hile the individual mutations present in . . . Omicron . . . were not associated with escape from ADG20 in the context of an original strain of the virus, new data show that the combination of mutations present in the Omicron spike protein led to a reduction in ADG20 neutralization that was not suggested by prior data." ECF 32, ¶ 62; ECF 38-7, at 1. To the extent the plaintiffs argue that this discovery proves that the defendants' statements regarding ADG20's predicted efficacy were misleading—at the time they were made—that argument fails. In determining whether statements are misleading, the Court must "consider the entirety of the relevant facts available *at the time of the allegedly misleading statement*," with a focus on what the defendants "*knew at the time*." *Ponsa-Rabell*, 35 F.4th at 33 (emphases added). The plaintiffs "'may not plead fraud by hindsight.'" *Id.* (quoting *ACA Fin. Guar. Corp.*, 512 F.3d at 62).

The plaintiffs' argument that the defendants failed to promptly disclose the *in vitro* testing results also lacks force. "While a company need not reveal every piece of information that affects anything said before, it must disclose facts, if any, that are needed so that what was revealed [before] would not be so incomplete as to mislead." *In re Cabletron Sys., Inc.*, 311 F.3d 11, 36 (1st Cir. 2002) (citations and quotation marks omitted). Where a duty arises to disclose facts related to later developments, the company is entitled to "a reasonable period of time . . . to make [its] disclosures." *New Jersey Carpenters Pension & Annuity Funds v. Biogen IDEC Inc.*, 537 F.3d 35, 57-58 (1st Cir. 2008) (finding a ten-day period to be a reasonable amount of time). Assuming the defendants had a duty to disclose the *in vitro* testing results so as to render their prior predictions

not misleading, they fulfilled their duty when they disclosed the results in the December 14 Press Release—just five days (and only three business days) after they received the results from Oxford on December 9, 2021. ECF 32, ¶¶ 59(c), 62. The plaintiffs offer no authority suggesting that five days is not a reasonable amount of time.

B. Scienter.

The plaintiffs' failure to adequately allege a materially false or misleading statement or omission alone requires dismissal of their complaint. But even if the defendants' statements or omissions regarding ADG20's efficacy against Omicron had been materially false or misleading, the complaint also fails to state sufficient facts to plead scienter, the second element of a section 10(b) and Rule 10b-5 claim.

Under the PSLRA, to plead scienter, the complaint must "with respect to each act or omission . . . state with particularity facts giving rise to a *strong* inference that the defendant acted with the required state of mind." 15 U.S.C. § 78u-4(b)(2)(A) (emphasis added). "Scienter is 'a mental state embracing intent to deceive, manipulate, or defraud.'" *Shash*, 84 F.4th at 13 (quoting *Mehta*, 955 F.3d at 206). "To establish scienter, plaintiff must 'show either that the defendants consciously intended to defraud, or that they acted with a high degree of recklessness.'" *Carbonite, Inc.*, 22 F.4th at 8 (quoting *Kader v. Sarepta Therapeutics, Inc.*, 887 F.3d 48, 57 (1st Cir. 2018)). "In this context, recklessness requires more than 'simple, or even inexcusable, negligence'; rather, recklessness is 'a highly unreasonable omission' amounting to 'an extreme departure from the standards of ordinary care, and which presents a danger of misleading buyers and sellers that is either known to the defendant or is so obvious that the actor must have been aware of it.'" *Shash*, 84 F.4th at 13 (quoting *Mehta*, 955 F.3d at 206). "An inference of scienter is 'strong' if 'a reasonable person would deem [it] cogent and at least as compelling as any opposing inference

one could draw from the facts alleged.'" *Fire & Police Pension Ass'n of Colorado*, 778 F.3d at 240-41 (quoting *Tellabs*, 551 U.S. at 324).

Often in cases where the scienter pleading standard is satisfied, the complaint "contains clear allegations of admissions, internal records or witnessed discussions suggesting that at the time they made the statements claimed to be misleading, the defendant officers were aware that they were withholding vital information or at least were warned by others that this was so." *In re Boston Sci. Corp. Sec. Litigation*, 686 F.3d 21, 31 (1st Cir. 2012). "[T]he fact that a defendant knowingly made a false statement is 'classic evidence' of scienter." *ACA Fin. Guar. Corp.*, 512 F.3d at 65 (quoting *Aldridge v. A.T. Cross Corp.*, 284 F.3d 72, 83 (1st Cir. 2002)). "[W]here a complaint is devoid of any direct-evidence allegations, the indirect-evidence allegations in the complaint will need to do more work to carry the burden of raising a strong inference of scienter on their own." *Shash*, 84 F.4th at 16 (quotation marks omitted).

The SAC is devoid of allegations resembling direct evidence of scienter. The plaintiffs nevertheless offer several arguments to advance their position that the facts alleged in the SAC support a strong inference of scienter. First, relying on *Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 49 (2011), they argue that the defendants' decision to announce ADG20's likely effectiveness against Omicron, when the defendants "had not evaluated existing data in the manner necessary to reasonably support such a belief," demonstrates a high degree of recklessness. ECF 39, at 17. In *Matrixx*, the defendant company did not disclose affirmative reports that its drug product had caused anosmia (loss of smell). 563 U.S. at 49. After receiving such reports, the company took a series of actions that, "taken collectively, g[ave] rise to a cogent and compelling inference that [the company] elected not to disclose the reports of adverse events not because it believed they were meaningless but because it understood their likely effect on the market." *Id.*

(citations and quotation marks omitted). Those actions included hiring a consultant to review the product; convening a panel of physicians and scientists; and issuing a press release that suggested studies had confirmed that the product did not cause anosmia, when it had not conducted any such studies and a panel of scientists thought the scientific evidence at the time was insufficient to determine whether it caused anosmia. *Id.*

In contrast, as alleged in the SAC, the defendants here had no conclusive evidence that ADG20 was ineffective against Omicron at the time of their statements. The contemporaneous warnings of public health excerpts lacked certainty: Dr. Collins said on *Fox News Sunday* that Omicron "*might* not respond as well to protection from the vaccines," and Dr. Fauci said on *Meet the Press* that Omicron "*might* evade immune protection that you would get, for example, from a monoclonal antibody." ECF 32, ¶¶ 47-48 (emphases altered). Neither were the defendants' statements regarding ADG20's likely effectiveness conclusive; instead they used forward-looking and hedging language like "expects," "anticipates," and "likely," while warning that the supporting data was "yet to come." ECF 32, ¶¶ 50-51, 54-55, 58; *see City of Dearborn Heights Act 345 Police & Fire Ret. Sys. v. Waters Corp.*, 632 F.3d 751, 760 (1st Cir. 2011) ("'[A]ttempts to provide investors with warnings of risks generally weaken the inference of scienter.'" (quoting *Ezra Charitable Tr. v. Tyco Int'l, Ltd.*, 466 F.3d 1, 8 (1st Cir. 2006))). Thus, *Matrixx* does not advance the plaintiffs' argument that the defendants acted with the requisite scienter.

Next, relying on *Carbonite*, the plaintiffs argue that the defendants acted with a high degree of recklessness because they were "paying close attention" to ADG20, as Adagio's lead product candidate, such that their public statements about ADG20's effectiveness against Omicron "invited further investigation." 22 F.4th at 9-10 (quotation marks omitted). In *Carbonite*, the First Circuit explained that "'the importance of a particular item to a defendant can support an inference that

the defendant is paying close attention to that item, if 'that close attention would have revealed an incongruity so glaring as to make the need for further inquiry obvious.'" *Id.* at 9 (quoting *Loc. No. 8 IBEW Ret. Plan & Tr. v. Vertex Pharms., Inc.*, 838 F.3d 76, 82 (1st Cir. 2016)). But, to support an inference of scienter, "the complaint must allege particular facts strongly suggesting that that attention exposed [the defendants] to information that either rendered their public statements false or necessarily invited further investigation." *Id.* at 9-10. The defendants in *Carbonite* had publicly touted that their important product was "super strong," but, at the time of their statement, the product had never once worked and employees who were working on the product had reported internally that the product was not ready for market. *Id.* at 10. Those alleged facts, the First Circuit reasoned, dispelled "the possibility that [the company's] management was somehow in the dark about [the product's] true status" at the time of their remarks, thus supporting an inference that the defendants were at least highly reckless. *Id.*

Here, in contrast, the SAC does not allege that ADG20 never worked. ADG20 had been successful in combatting all variants prior to Omicron, including the Alpha, Beta, Delta, and Gamma variants. ECF 32, ¶¶ 33-34. The SAC contains no allegations that, at the time of the relevant statements, Adagio, Dr. Gerngross, Dr. Walker, or any employee at Adagio knew or reported that ADG20 was unlikely or not going to be effective against Omicron. Thus, notwithstanding ADG20's status as a lead product candidate of Adagio, the facts alleged in the SAC do not support an inference, on a "core operations" theory, that defendants knew, or were reckless in not knowing, that ADG20 would be ineffective against Omicron. *See Metzler Asset Mgmt. GMBH v. Kingsley*, 928 F.3d 151, 165 (1st Cir. 2019) (concluding plaintiffs failed to establish scienter on a "core operations" theory where "plaintiffs fail[ed] to identify any allegations

in the complaint that show[ed] that anyone in the company had knowledge regarding the drug's safety profile and sales that contradicted the company's public representations").

The plaintiffs next contend that because Omicron was so unlike the earlier variants of SARS-CoV-2 in terms of the number and location of its mutations, it was "incredibly reckless" for the defendants to tout ADG20's predicted effectiveness without first analyzing Omicron's structural data or warning investors that it had not conducted such a review. ECF 39, at 18. But to establish recklessness, the plaintiffs must plead "more than simple, or even inexcusable, negligence." *Shash*, 84 F.4th at 13 (quotation marks omitted). In this context, the plaintiffs must allege facts establishing "a highly unreasonable omission amounting to an extreme departure from the standards or ordinary care" that "presents a danger of misleading buyers and sellers that is either known to the defendant[s] or is so obvious that [they] must have been aware of it." *Id.* (quotation marks omitted).

As alleged in the SAC, the defendants were transparent in their statements on November 29 and December 1, 2021 regarding the basis for their predictions about ADG20's efficacy against Omicron. The November 29 Press Release stated that Adagio's expectations were "[b]ased on published epitope mapping and structural studies," as well as ADG20's performance against "other variants of concern identified previously." ECF 32, ¶¶ 50-51 (emphases omitted). The December 1 Gerngross Evercore Statements similarly reflect that Dr. Gerngross told conference attendees that "[t]he data on [Omicron] as far as localization [was] yet to come," such that his predictions were based on "everything that [they had] seen so far up to [that] point." *Id.* ¶ 58 (emphasis omitted); ECF 38-6, at 1. The SAC does not allege that the defendants had data that discredited their view that ADG20 would retain neutralization activity against Omicron. Nor does the SAC allege that the defendants believed—at the time of their statements—that Omicron's mutation

characteristics in any way undermined their belief that ADG20 would continue to neutralize against Omicron. Taken together, these facts do not suggest that the defendants' statements "present[ed] a danger of misleading buyers and sellers that [was] either known to the defendant[s] or [was] so obvious that [they] must have been aware of it." *Shash*, 84 F.4th at 13, 17 (quotation marks omitted) (scienter could not be inferred from defendants' failure to disclose subgroup results where defendants were "transparent about what data [they were] withholding from investors," "the complaint lack[ed] any indication that Defendants believed the subgroup data undermined their efficacy statements," and defendants' analysis was "not fully discredited by the subgroup data").

The plaintiffs additionally argue that certain statements in the December 14 Press Release serve as evidence of scienter. ECF 39, at 19. Emphasizing the defendants' December 14 statement that "the combination of mutations present in the Omicron spike protein led to a reduction in ADG20 neutralization that was not suggested by prior data," ECF 32, ¶ 62, the plaintiffs counter that a *true* analysis of the "combination of mutations" documented in "prior data" would have confirmed that ADG20's neutralization of Omicron was unlikely. Thus, the December 14 Press Release, the plaintiffs contend, contains a false and misleading justification for the discrepancy between its ADG20 efficacy predictions and the ultimate *in vitro* testing results. And, the plaintiffs argue, providing a false and misleading justification for earlier statements can support an inference that the defendant sought to "cover-up" their "misdeeds," which is strong evidence of scienter. ECF 39, at 19 (citation and quotation marks omitted).

The Court disagrees with the premise of the plaintiffs' argument—namely, that the identified statement in the December 14 Press Release was false and misleading. The first sentence of the paragraph in which the statement appears reads: "'Due to the highly conserved and immunorecessive nature of the epitope recognized by ADG20, we anticipated that ADG20 would

retain neutralizing activity against Omicron, consistent with activity observed in *in vitro* models with all other variants of concern.'" ECF 38-7, at 1. Thus, read in the context of the full release, the defendants' reference to "prior data" reasonably refers to the *in vitro* models that Adagio observed for all other variants of concern. The SAC is devoid of allegations indicating the prior *in vitro* models—or any other prior data that Adagio consulted—demonstrated that ADG20's neutralization of Omicron was unlikely. To the extent the plaintiffs scientifically disagree, their own scientific opinion does not render defendants' opinion misleading. *See Shash*, 84 F.4th at 17 ("[A] legitimate disagreement over scientific data does not give rise to a securities fraud claim." (quotation marks omitted)).

Finally, insofar as the plaintiffs suggest that the Oxford *in vitro* test results themselves create an inference of scienter, that argument amounts to impermissible "fraud by hindsight." "Fraud by hindsight refers to allegations that assert no more than that because something eventually went wrong, defendants must have known about the problem earlier. '[A] plaintiff may not simply contrast a defendant's past optimism with less favorable results, and then 'conten[d] that the difference must be attributable to fraud.'" *Mississippi Pub. Employees' Ret. Sys.*, 523 F.3d at 90 (quoting *Shaw v. Digital Equip. Corp.*, 82 F.3d 1194, 1123 (1st Cir. 1996)). That the *in vitro* results ultimately demonstrated that ADG20 was markedly less effective against Omicron is not evidence that the defendants intended to defraud or acted with a high degree of recklessness when they made their prior statements. Thus, the SAC does not plead sufficient facts to establish scienter, and the plaintiffs' claims under section 10(b) and Rule 10b-5 must, accordingly, be dismissed. And, without a viable section 10(b) and Rule 10b-5 claim, the plaintiffs' section 20(a) claim must be dismissed as well. *ACA Fin. Guar. Corp.*, 512 F.3d at 68.

III. Leave to Amend.

Federal Rule of Civil Procedure Rule 15(a) provides, "[t]he court should freely give leave [to amend] when justice so requires." Fed. R. Civ. P. 15(a)(2). Although "[t]he rule reflects a liberal amendment policy," the Court "enjoys significant latitude in deciding whether to grant leave to amend." *ACA Fin. Guar. Corp.*, 512 F.3d at 55. Having already been afforded two opportunities to amend the complaint, the plaintiffs nevertheless request leave to file a third amended complaint if the Court were to grant the motion to dismiss. ECF 28; ECF 32; ECF 39, at 20. The plaintiffs do not, however, identify any additional substantive allegations that would be included in a possible third amended complaint. Nor do they offer any argument as to why justice otherwise requires amendment. Accordingly, the request for leave to amend is denied. *See ACA Fin. Guar. Corp.*, 512 F.3d at 56 ("Grounds for denial include 'undue delay, bad faith or dilatory motive . . . repeated failure to cure deficiencies by amendments previously allowed, undue prejudice to the opposing party . . . [and] futility of amendment.'" (quoting *Foman v. Davis*, 371 U.S. 178, 182 (1962))).

CONCLUSION AND ORDER

For the foregoing reasons, the defendants' motion to dismiss, ECF 36, is GRANTED. The second amended complaint is DISMISSED with prejudice and without leave to amend.

SO ORDERED.

/s/ Julia E. Kobick
JULIA E. KOBICK
UNITED STATES DISTRICT JUDGE

Dated: September 18, 2024